RULE 131 AFFIDAVIT

In the United States Patent and Trademark Office

Applicant:	Richard J. Arnott	Examiner:	Hoekstra, J.
Serial No.:	10/698,835	Art Unit:	3736
App. Filing Date:	10/31/2003		
For:	Quick-release torquer apparatus for delivering and maintaining a medical guidewire		

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313

AFFIDAVIT UNDER 37 CFR § 1.131

I, Richard J. Arnott, being duly sworn depose and say:

That I am the sole inventor of the above-identified patent application;

That I conceived in the United States the invention claimed in the above-identified patent application prior to the effective filing date of prior art U.S. Patent Publication No. 2003/0229297 A1 ('297). Specifically, my documented date of conception of June 19, 2001 pre-dates the '297 effective filing date of March 19, 2002, which, in the Examiner's view, discloses but does not claim my invention. '297 published on December 11, 2003, only 3 months after my filing date.

Attached are exhibits that show my conception and diligent reduction to practice of the invention as claimed, including *inter alia* the claimed features of the two arms, the horizontal slit defined within the flap hinge, the vertical slit in the clamping tongue, and the wire channel means.

Exhibit 1, dated 6/19/2001, is an original copy of a bound notebook page providing a sketch of my invention, showing the two slots and the "guide teeth". Note, although an informal sketch, this is very similar to figure 5 filed for my above-identified patent application.

Exhibit 2, dated 8/1/2001, is a hand mark-up of more drawings showing the continued development of the invention's longitudinal grooves and slots.

Exhibit 3, dated 10/25/2001, is an email from an interested party reviewing the invention concept under confidentiality, acknowledging the invention's features of, *inter alia*, quick release to the side of the wire without having to slide off the end [using the vertical and horizontal slits], the clamp and locking device, and one-hand release.

Exhibit 4, dated 1/18/2002 (the date of 1/18/2001 is a typographical error), is minutes of a meeting with a patent attorney whom I originally sought to prepare the patent application for my invention.

Exhibit 5, dated 1/24/2002, is the client intake form prepared after the attorney consultation for the matter concerning my medical guide wire clamp invention.

Exhibit 6, dated 10/8/2002, is a financial statement reflecting the production of an ongoing series of formal drawings prepared for the invention over the course of the summer of 2002 and completed on 9/25/2002.

Exhibit 7 is the start to the drafting of the specification that was to be compiled by my former patent counsel over the course of 2002 to early 2003. Unfortunately, my patent counsel became terminally ill and I retained alternate patent counsel in September of 2003.

Exhibit 8, dated 9/16/2003 is an order form documenting a patent search update performed by my new counsel, who soon thereafter prepared and filed the above-identified application on 10/31/2003.

That exhibits 1-8, which relate to the aforementioned conception, reduction to practice, and diligence, correspond to the invention broadly disclosed and claimed in the above identified patent application.

/s/ Richard J. Arnott

Sworn and subscribed to before me this 23rd day of August 2006.

Anna Mae Schmitt
Notary Public

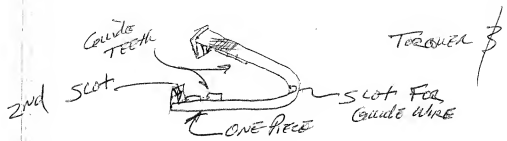
COMMONWEALTH OF PENNSYLVANIA
Notarial Seal
Anna Mae Schmitt, Notary Public
Baldwin Twp., Allegheny County
My Commission Expires Jan. 19, 2010
Member, Pennsylvania Association of Notaries

6-18-01

Jim Logan.
- Called Left message

6-19-01

Tom Hockin 9:30
Final Machine
Radiation - Chuck.



Jim Logan
Rudy Kravys
George Atwell

QOSINA

August 1, 2001

Mr. Richard Arnott
MEDICAL DEVICES TECHNOLOGY
113 Hodil Ter
Pittsburgh, PA 15238

Dear Mr. Richard Arnott:

Hello from Qosina Corporation! Please find enclosed your requested component sample(s):

#72975 Catheter Clamp w/drawing

If you need any further details or samples of our products, please do not hesitate to contact our office. We look forward to doing business with you.

Sincerely,

Ed Lu

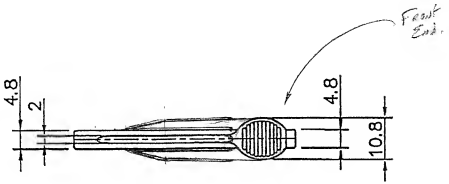
Ed Lu
Business Development Manager

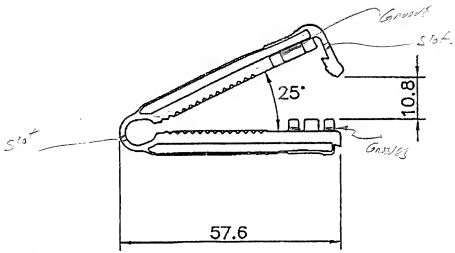
EL/lm

150-Q EXECUTIVE DRIVE, EDGEWOOD, NEW YORK 11717-8329 U.S.A.
PHONE (631) 242-3000 • FAX (631) 242-3230
info@qosina.com • www.qosina.com

REVISIONS

LTR	DATE	DESCRIPTION	APPROVED
-	3/2000	Initial Release	A.V.





QOSINA CORP.
150-D EXECUTIVE DRIVE, EDGEWOOD, NY 11717

DESCRIPTION
Catheter Clamp

SIZE	FSCM NO.	PART NO.
A		72975

DATE	CHECKED	
3-10-00	G.H.	DO NOT SCALE DRAWING

Date: Thu, 25 Oct 2001 15:09:18 -0700 (PDT)
From: "richard arnott" <richardarnott@yahoo.com> | **Block Address** | **Add to Address Book**
Subject: Concept details
To: "Amr Salahieh" <asalahieh@embolic.com>

Amr,

Please see the following in response to you request for detail on the various concepts that I provided during my visit. I believe that this incorporates most of the details however, I may have forgotten one or two points. Please review this with Fred for accuracy.

Richard

Richard J. Arnott

113 Hodil Terrace

Pittsburgh, PA 15238

October 25, 2001

Re: Arnott product idea details.

Dear Amr,

Thank you for your hospitality, the trip back was long but pleasant.

I have yet to get a copy of the EPI Confidentiality Agreement signed by Fred and myself while I was in San Jose. Please forward to me a copy of that signed agreement for my files.

In response to your e-mail of 10-23-01 requesting detail of the various concepts, remember that these projects are in their concept stages and t[illegible]is required for each one. Please see the following for details:

EXHIBIT 3

Clip on Torquer

Quick release device. Releases to side of wire without having to slide off the end of the

Guide wire.

Hugs guide wire when clamping is released. This allows for easy sliding along guide wire without it falling off.

Can also be used in a conventional manner as a slide over the end of the wire, Torquer.

Doubles as a catheter clamp.

Lever type locking design allows for greater locking pressure without kinking wire..

One piece design, less handling and expense for manufacturing. Can also add abrasive strips like those used on the "Rotablator" if desired.

Simple, comfortable, human friendly design.

One hand release.

Quick market entry.

High number of sales, ROI open to market demand.

Easy USA manufacture.

Low tooling investment.

Introducer Cuff

Large mouth spoon guide. Thus allowing for easy entry into an introducer by a bent floppy tip of a guide wire.

Rolled tubular section, with side slit, that fits into introducer.

Made from same process as drinking straws, easy to manufacture.

One piece construction.

Quick market entry.

One piece distal protection filter.

Molded design, injection molding or combination molding.

Modular design, different from existing technology.

Jan 18, 2001

George Atwell And Richard Arnott

Re: Friday meeting,

Existing Patent Application:

1. When more than one inventor is listed on a Patent does the position or order of inventorship matter?
   Ex: 1st name denotes most contribution?
   2nd name, second in contributions?
   3rd name , third in contributions?
2. How is the % of ownership determined? By the % of the number of claims?
3. Show George Patent Application.
   a.) Name position.
   b.) Claims - References to pull wire and other components. How do you determine ownership of the claim when part is yours and part is not?

Torquer patent application:

1. Previous Patent Application - Description of general procedure in the Field of the invention and in the description of the prior art (highlighted areas). Can we use in description of our Torquer…good start.
2. Show George Torquer again.
3. Show George initial Patent search results.
4. Show George lists of Torquer benefits.
5. Next step?

Burton conference call:

1. Telephone Steve Barsotti 12:40PM - 12:45 PM Cell Phone (412) 512-3377
   a.) Quick review if Burton's agenda.
   b.) Open discussion.
1. No lead person…Just listen to Burton.
2. Don't volunteer any information.
3. Tape recorder in place.
4. Call Burton - Left message on my answering machine.
   a.) (877) 251-2389 For conference call.
   b.) Conference code: 888-545-5554 then # sign.
   c.) Music hold until they are ready.

Review Patent Items.

Richard J. Arnott

113 Hodil Terrace
Pittsburgh, PA 15238

1. Clip on Torquer
   a.) Quick release device. Releases to side of wire without having to slide off the end of the Guide wire.
   b.) Hugs guide wire when clamping is released. This allows for easy sliding along guide wire without it falling off.
   c.) Can also be used in a conventional manner as a slide over the end of the wire, Torquer.
   d.) Doubles as a catheter clamp.
   e.) Lever type locking design allows for greater locking pressure without kinking wire.. •
   f.) One piece design, less handling and expense for manufacturing. Can also add abrasive strips like those used on the "Rotablator" if desired.
   g.) Simple, comfortable, human friendly design.
   h.) One hand release.
   i.) Quick market entry.
   j.) High number of sales, ROI open to market demand.
   k.) Easy USA manufacture.
   l.) Low tooling investment.

need date of conception
Shown to: Synovis
EPI (div of Boston Scientific?)
Dr. Mark Woolley
(all subject to confidentiality ?)

NEW MATTER REPORT

CLIENT INFORMATION

CLIENT: Richard J. Arnott
Date: Jan 24 2002
ADDRESS: 113 Hodil Terrace
( ) NEW CLIENT (X) PRESENT CLIENT
Pittsburgh (City) PA 15238 (Code)
SOC. SEC. #
BUSINESS PHONE:
CLIENT NUMBER
CONTACT: FAX: (412) 963-6368
HOME PHONE: (412) 963-7287

MATTER INFORMATION

FILE NAME:
NATURE OF MATTER: Medical Guide Wire Clamp
AMOUNT INVOLVED:
REFERRED BY:
OPPOSING PARTY: Name Address Phone No.
OPPOSING LAWYER: Name Address Phone No.

FEE ARRANGEMENT

( ) FIXED FEE OF $ OR RANGE OF $ TO $
( ) TIME RATE
( ) CONTINGENCY OF:
( ) FEE TO BE DETERMINED ON BASIS OF WORK DONE, TAKING INTO ACCOUNT ALL RELEVANT FACTORS.
( ) OTHER:
CLIENT SIGNATURE
ESTIMATED FEE $

BILLING PROCEDURE

( ) NEW GENERAL RETAINER $ PER EFFECTIVE
( ) OPENING ADVANCE OF $
( ) BILLING INSTRUCTIONS FOR BOOKKEEPER:

	MONTHLY	QUARTERLY	UPON CONCLUSION	OTHER
FEE	( )	( )	( )	( )
DISBURSEMENTS	( )	( )	( )	( )

OTHER:

FILES

FILE CARDS PREPARED BY: DATE
( ) OPEN NEW FILE ( ) INCLUDE IN EXISTING FILE ( ) NO FILE
FILES CHECKED FOR CONFLICT OF INTEREST BY: DATE

FIRM ADMINISTRATION

OPENED BY
ENGAGEMENT RECEIVED FROM
RESPONSIBLE LAWYER
ENGAGEMENT RECEIVED BY
ASSIGNED LAWYERS
COMMENTS

EXHIBIT
tabbies
5

STATUTE OF LIMITATIONS DATE

ATWELL & MORROW, P.C.
Attorneys at Law
421 North Main Street
P.O. Box 829
Butler, Pennsylvania 16003
(724) 283-9333

DRAFT

STATEMENT

To: **RICHARD J. ARNOTT**
113 HODIL TERRACE
PITTSBURGH, PA 15238

Date: **OCTOBER 8, 2002**

For Legal Services: **OUR FILE NO. 02-004**
"TORQUE DEVICE"

PATENT DRAFTSMAN:

	Drawings to date	$ 750.00
09/25/02	RETAINER RECEIVED – Check No. 2845	- 750.00
	(Total check in the amount of $2,000.0 - $1,250.00 was credited to File No. 92-036 – Pending Patent Application)	-0-

Total Due	$ 750.00
Less: Payment Credit	- 750.00
Balance	$ 0.00
Interest Charge	0.00
Balance Due	**$ 0.00**

MEDICAL GUIDE WIRE TORQUER

METHOD AND APPARATUS FOR DELIVERING AND MAINTAINING A MEDICAL GUIDE WIRE TO AND BEYOND AN OPERATIVE SITE UTILIZING A QUICK ATTACH/RELEASE DEVICE

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention is directed to a method and apparatus for delivering, manipulating and repositioning a guide wire to and beyond an operative site in any of a variety of medical procedures employed to treat any number of medical conditions in human and/or animal patients.

2. Description of the Prior Art

In many medical procedures, endovascular devices are delivered during diagnostic and surgical procedures, and it is useful and/or necessary to deliver these devices over a medical guide wire.

Minimally invasive interventional medical diagnosis procedures in general, and minimally invasive endovascular therapy in particular, are medical events where devices are delivered over a guide wire during the procedure, each has enjoyed unprecedented expansion to treat patients because of the numerous medical benefits associated with not having to enter the body through more invasive surgical techniques. These benefits include, but are not limited to, less trauma and/or scarring for patients, less " time to heal, less risk of infection and decreased hospital stays, to name but a few.

More particularly, minimally invasive endovascular therapy is often used to treat diseased vessels, e.g., arteries and veins. With such therapy, small instruments are inserted into the vessels through a puncture or access opening made in one of the vessels at an entry site and are advanced through the circulatory system to an operative site where the vessel has become diseased, and the instruments are used to diagnose and repair the diseased or operative site.

Typically, the goal of such therapy is to identify and dilate full or partial blockages of the diseased vessel. Such blockages may have developed over time or may have developed quickly, as for example, in response to an injury. One common source of such blockage is thromboemboli which has formed in the vessel. Thrombus is an aggregation of platelets, fibrin. clotting factors and cellular components of blood that spontaneously form and attach on the interior wall of a vein or artery, and thromboemboli are emboli of thrombus which operate to partially or completely occlude the interior or lumen of the blood or other
.vessel.

Techniques to open and/or maintain the dilation of the partially or completely occluded lumen of blood or other vessels include delivering a balloon over a guide wire and positioning it across an obstruction or partially occluded section of the vessel, inflating the balloon to compress the build up (balloon angioplasty) and/or temporarily or permanently inserting, again over a guide wire, a tube-like support within the vessels to keep the vessel open (stenting).

Minimally invasive endovascular [redacted] significant advantage that they are less invasive than traditional surgical techn[redacted] to the patient. However, these procedures are complicated by the fact that [redacted]c the vessel wall or dislodge and

free particles/objects during the procedures as discussed above, and in that the tools or instruments and workspace, e.g., the interior of the vessels of the body, are in some cases extremely small and close, and reaching the operative site with the tools is very difficult in some instances due to the considerable branching of the circulatory system that may occur between the entry site into the blood vessel and the operative site. Endovascular diagnosis and therapy is further complicated by the fact that the entry site is often far from the operative site, as for example, where the entry site is in the thigh at the femoral artery and the operative site is located in the neck at the carotid artery. Even when the surgeon's instruments have been properly advanced to the operative site, manipulating the tools to perform their respective functions at the operative site is often difficult for the surgeon due to many factors including guide wire movement, the close quarters at the operative site and the distance between the entry site and the operative site.

One method and apparatus commonly used by surgeons to ensure the tools reach the operative site is to first thread a simple guide wire to or beyond the operative site. Thereafter, various tools are threaded over the guide wire by the surgeon to reach the operative site. It is an important aspect of such guide wires that they must be easy to manipulate through the vessels, including in certain cases, through lesions or areas of blockage in the vessel by the surgeon. In addition to exhibiting sufficient resiliency so as to be pushable in the vessel, the guide wire must exhibit sufficient flexibility and maneuverability to enable the surgeon to traverse .the many twists and turns of the circulatory (or other) system to reach the operative site.

A major aspect of the ability for a surgeon to manipulate the guide wire through the circulatory or other system is the guide wire's "torquability" .As defined herein, the term "torquability" means that as the surgeon rotates the proximal region of the guide wire that extends outside of the patient's body during the advancement of the guide wire through the patient's blood or other vessels to the operative site, the amount of rotation at the proximal region of the guide wire is transmitted to the distal end of the guide wire being inserted and advanced through the patient's blood or other vessels to the operative site. A lack of correlation between rotation at the proximal region of the guide wire and rotation at the distal end of the guide wire is referred to as reduced torquability and is undesirable. A high degree of correlation is referred to as a high degree of torquability and is desirable. As may be appreciated, it is most desirable for the guide wire to have an exact correlation or high torquability between the rotation applied proximally at the proximal region of the guide wire and the rotation developed distally in the guide wire, so that the surgeon can carefully control and direct the medical guide wire. With known devices, there is considerable difference between the amount of rotation applied at the proximal region of the guide wire and the amount of rotation developed at the distal end of the guide wire, making it very difficult for surgeons to maneuver the distal end of the guide wire.

Even where the guide wire exhibits the desired torquability characteristics, and the tools have been properly threaded to the operative site and have been properly manipulated to perform their respective functions at the operative site, there remains the problem noted above, namely, that the process of dilating the occlusion and/or inserting the stent may dislodge or free small particles or objects, also known, among other things, as clots, fragments, plaque, emboli, thromboemboli, etc. More particularly, with respect to endovascular therapy, the term "embolic event" has come to be used to describe complications where thrombus or plaque is shed inadvertently from a lesion to migrate to smaller vessels beyond the operative

site to create a full or partial occlusion of the lumen of the vessel or vessels. This is most undesirable and can lead to many complications. Complications depend upon the site in the body where such emboli lodge downstream of the operative site, but may include stroke, myocardial infarction, kidney failure, limb loss or even death. With increasing vigor, surgeons have expressed the need to reduce the likelihood of such complications so that protection against embolic events will become a standard component of endovascular therapy.

Devices have been made in the art to capture objects, including emboli, downstream of an operative site in medical procedures, including endovascular therapy. Such devices generally employ a capture device, such as a bag or filter, which has a collapsed state and an expanded or deployed state. Typically, the capture device is maintained in its collapsed state within sheathing and is inserted into the blood or other vessel and is threaded beyond the operative site. It is then ejected from the sheathing whereupon it expands to its deployed state to capture the objects dislodged or otherwise freed during the medical procedure.

[0012] One device for removing clot or filtering particles &om blood is '" described in U.S. Patent No.4, 723,549 to Wholeyet al.. which discloses a device for dilating

. .aded blood vessels. This device includes a collapsible filter device positioned between a dilating balloon and the distal end of the catheter. The filter comprises a plurality of resilient ribs secured to the catheter that extend a:x:ially toward tire dilating balloon. Filter material is secured to the ribs. The filter deploys as a balloon is inflated to *form* a cuP-shaped trap. An important limitation of the Wholey et al. device appears to be that the :filter does not seal around the interior vessel wall. Thus, particles sought to be trapped in the filter can instead undesirably pass between the filter and the vessel wall and flow d~ in the circulatory system to produce a blockage. Another limitation is that the device also presents

a large pro.file during positioning. Yet another limitation appears to be that the device is difficult to construct.

lOO13] u.s. Patent No. 4.873,978 to Ginsburg discloses a vascular catheter that includes a strainer device at its distal end. The device is inserted into a vessel downstream from the treatment site and advanced to a proximal downstream location. The filter is contained in a sheath when closed. When pushed from the sheath, the filter deploys such th~t its mouth spans the lumen of the vessel. Deployment is by expansion of resilient

'" tines to which the strainer material is attached. Again, however, it appears that the filter does not seal around the interior vessel wall. thus undesjrably allowing pm1icles to bypass the filter by passing between the filter and the vessel wall. The position of the mouth relative to the sheath is also clinically limiting for the Ginsburg device.

10014] U.S. Patent No. 5,695,519 to S~ers et al. discloses a removable intravascular filter on a hollow guide wire for entrapping and retaining oli. The filter is deployable by manipulation of an actuating wire that extends from the filter into and through the hollow tube and *out* the proximal end. One limitation with the Summers et at device appears to be that its filter material is not fully constrained. Therefore, during positioning within a vessel. as the device is positioned through and past a clot. the .filter material can snag clot matcrial undesirably creating fleely floating emboli. It is *wwlear if* the actuating wire can close the filter, and it appears in any event that it will exert a pull force on the rim of the filter that could tear the wire from the rim. Another limitation appears to be that the device application is limited by the diameter of the tube needed to contain the actuating wire.

[0015] U.S. Patent No. 5,814,064 to Daniel et al. discloses an cmboli Capture device on a guide 'Wire. The filter material is coupled to a distal portion of the guide wire and ~ is expanded ~cross the lumen of a vessel by a fluid activated expandable member in

Web Order

Patent/Trademark Request

Date:	9/16/2003
Client:	McKay & Associates
Contact:	Don McKay
Docket:	2344
Phone:	412-344-6113
Delivery	USMail

Document No.			
	6030349	5161534	5312338
	5325868	5325746	5579780
	5606980	5634475	4723549
	4873978	5695519	5814064

Comments: